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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,353	01/28/2000	Jeffrey M. Linnen	CDS-211	2146

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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT PAPER NUMBER

1634

DATE MAILED: 05/14/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/493,353

Applicant(s)

LINNEN ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED April 22, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 22 April 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.


3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☒ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: none.
- Claim(s) objected to: none.
- Claim(s) rejected: 1-64.
- Claim(s) withdrawn from consideration: none.
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

Continuation of 2. NOTE: The amendments to Claims 1, 9, 27, 35, 43, 54 have been amended to delete reference to SEQ ID NO: 3 (C143F26), 5, 6. This amendment raises a 112/2 issue with respect to Claims 7, 13, 33, 39, 47, 48, 58, 59, for example because the claims depend upon the amended claims, however remain directed to the deleted sequences.

Continuation of 5. does NOT place the application in condition for allowance because: The applicant has filed a declaration under 1.132 which has been thoroughly reviewed, but found non-persuasive. It is noted in MPEP 716.01 that a 1.132 declaration and other evidence traversing the rejections are considered timely if submitted prior to a final rejection.

The instant declaration, however, has been reviewed. The declaration provides analysis to illustrate SEQ ID NO: 8 and 9 were superior primers as compared to other primers which were used by applicants. The MPEP provides in 716.02(e) a requirement of Comparison With Closest Prior Art. The MPEP states, "An affidavit or declaration under 37 CFR 1.132 must compare the claimed subject matter with the closest prior art to be effective to rebut a prima facie case of obviousness. In re Burckel, 592 F.2d 1175, 201 USPQ 67 (CCPA 1979). "A comparison of the claimed invention with the disclosure of each cited reference to determine the number of claim limitations in common with each reference, bearing in mind the relative importance of particular limitations, will usually yield the closest single prior art reference." In re Merchant, 575 F.2d 865, 868, 197 USPQ 785, 787 (CCPA 1978) (emphasis in original). Where the comparison is not identical with the reference disclosure, deviations therefrom should be explained. In re Finley, 174 F.2d 130, 81 USPQ 383 (CCPA 1949), and if not explained should be noted and evaluated, and if significant, explanation should be required. In re Armstrong, 280 F.2d 132, 126 USPQ 281 (CCPA 1960) (deviations from example were inconsequential). Applicant does not appear to have compared SEQ ID NO: 8 and 9 to the closest prior art, namely Tanaka (primers in Table 2) and Kolykhalov (primer 285, 284). The declaration has stated that primer 72R27 "gave very little or no gel bands", such that the primer pair of SEQ ID NO: 8 and 72R27 does not work. The declaration states that the band obtained using 66R25 and 67R25 appeared as broad smear and not as sharp distinct bands. The declaration states that SEQ ID NO: 8 and 9 yielded robust, clean bands. The declaration further states that "only the combination of forward primer 1F27 (SEQ ID NO: 8) and reverse primer 57R27 (SEQ ID NO: 9) successfully amplifies HCV nucleic acids with sufficient sensitivity and specificity for use, e.g., in clinical assay". It is noted that the declaration was not drawn to sensitivity or specificity, since the declaration was not drawn to detection of certain quantities of nucleic acids nor only HCV nucleic acids. The declaration illustrates that one primer pair did not work. The art teaches that Primer 7 and 11 were used (Tanaka, col 12). The primer 7 which was used and worked contains the same 5' end of the primer. Therefore, absent a comparison and explanation, it is unclear why the primers in the art work, while the primers in the declaration fail.

Moreover, MPEP 716.02(d), provides that the unexpected Results must be Commensurate in Scope With Claimed Invention. The claims drawn to single oligonucleotides, Claims 40-42, are not encompassed by the unexpected results of the specification, nor the asserted unexpected results of the declaration. The unexpected results are drawn to pairs of primers. Thus, single oligonucleotides are not commensurate in scope with the unexpected results.


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